

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application.

1.-27. (Cancelled)

28. (Currently Amended) A method of treating a respiratory illness in a mammal comprising the steps of:

(a) providing an aerosol composition, wherein said composition comprises aqueous droplets having a particle size of less than ten microns in diameter, wherein the aqueous droplets comprise:

- (i) water,
- (ii) crystalline particles of a therapeutic agent which is poorly soluble in water, wherein the crystalline particles have ~~a submicron~~ an effective average particle size of less than 1000 nm; and
- (iii) at least one surface modifier adsorbed on the surface of the crystalline therapeutic agent particles; and

(b) administering said aerosol composition to the lungs of said mammal,
wherein:

- (i) the respiratory illness is selected from the group consisting of asthma, emphysema, respiratory distress syndrome, chronic bronchitis, and cystic fibrosis, and
- (ii) the therapeutic agent is beclomethasone.

29. (Currently Amended) The method of claim 28, wherein the crystalline particles of a poorly soluble therapeutic agent have an effective average particle size of less than 400 nm.

30. (Currently Amended) The method of claim 29, wherein the crystalline particles of a poorly soluble therapeutic agent have an effective average particle size of less than 300 nm.

31. (Currently Amended) The method of claim 30, wherein the crystalline particles of a poorly soluble therapeutic agent have an effective average particles size of less than 100 nm.

32. (Previously Presented) The method of claim 28, wherein the surface modifier is selected from the group consisting of gelatin, casein, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor oil, polyethylene glycols, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, tyloxapol, a polymer, a polyoxamine, dextran, lecithin, a dialkylester of sodium sulfosuccinic acid, sodium lauryl sulfate, an alkyl aryl polyether sulfonate, a polyoxyethylene sorbitan fatty acid ester, a mixture of sucrose stearate and sucrose distearate, $C_{18}H_{37}CH_2(CON_9CH_3)CH_2(CHOH)_4(CH_2H)_2$, a sulfated block copolymer of ethylene oxide and propylene oxide, and a triblock copolymer of the structure - (PEO) (PBO) (PEO) - having a molecular weight of about 3800 to about 5000.

33. (Previously Presented) The method of claim 28 comprising at least two surface modifiers.

34. (Previously Presented) The method of claim 28, wherein the surface modifier is present at an amount of from about 0.1% to about 90% (w/w), based upon the total weight of the combined therapeutic agent and surface modifier.

35. (Previously Presented) The method of claim 34, wherein the surface modifier is present at an amount of from about 1% to about 75% (w/w), based upon the total weight of the combined therapeutic agent and surface modifier.

36. (Previously Presented) The method of claim 35, wherein the surface modifier is present at an amount of from about 20% to about 60% (w/w), based upon the total weight of the combined therapeutic agent and surface modifier.

37.-38. (Cancelled)

39. (Previously Presented) The method of claim 28, wherein the therapeutic agent is present in the aqueous medium at an amount of from about 0.1% to about 60% (w/w), based on the total weight of the therapeutic agent and surface modifier.

40. (Previously Presented) The method of claim 39, wherein the therapeutic agent is present in the aqueous medium at an amount of from about 5% to about 30% (w/w), based on the total weight of the therapeutic agent and surface modifier.

41. (Cancelled)

42. (Previously Presented) The method of claim 28, wherein step (a) further comprises:

- (1) providing a suspension of the particles of the therapeutic agent; and
- (2) nebulizing the suspension by a jet nebulizer to form the aerosol.

43. (Previously Presented) The method of claim 28, wherein step (a) further comprises:

- (1) providing a suspension of the particles of the therapeutic agent; and
- (2) nebulizing the suspension by an ultrasonic nebulizer to form the aerosol.

44.-50. (Cancelled)

51. (Previously Presented) The method of claim 28, wherein at least 90% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 400 nm.

52. (Previously Presented) The method of claim 28, wherein at least 95% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 400 nm.

53. (Previously Presented) The method of claim 28, wherein at least 99% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 400 nm.

54. (Previously Presented) The method of claim 28, wherein at least 90% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 300 nm.

55. (Previously Presented) The method of claim 28, wherein at least 95% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 300 nm.

56. (Previously Presented) The method of claim 28, wherein at least 99% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 300 nm.

57. (Previously Presented) The method of claim 28, wherein at least 90% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 100 nm.

58. (Previously Presented) The method of claim 28, wherein at least 95% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 100 nm.

59. (Previously Presented) The method of claim 28, wherein at least 99% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of less than 100 nm.

60. (Currently Amended) The method of claim 28, wherein the crystalline particles of a poorly soluble therapeutic agent have an effective average particle size selected from the group consisting of about 400 nm, about 300 nm, and about 100 nm.

61.-63. (Cancelled)

64. (Previously Presented) The method of claim 28, wherein at least 90% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 400 nm.

65. (Previously Presented) The method of claim 28, wherein at least 90% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 300 nm.

66. (Previously Presented) The method of claim 28, wherein at least 90% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 100 nm.

67. (Previously Presented) The method of claim 28, wherein at least 95% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 400 nm.

68. (Previously Presented) The method of claim 28, wherein at least 95% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 300 nm.

69. (Previously Presented) The method of claim 28, wherein at least 95% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 100 nm.

70. (Previously Presented) The method of claim 28, wherein at least 99% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 400 nm.

71. (Previously Presented) The method of claim 28, wherein at least 99% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 300 nm.

72. (Previously Presented) The method of claim 28, wherein at least 99% of the crystalline particles of a poorly soluble therapeutic agent have a particle size of about 100 nm.